Before the
Department of Health and Human Services
Centers for Medicare & Medicaid Services

In the Matter of	)	
	)	
Medicare and Medicaid Programs;	)	
Regulation to Require Drug Pricing Transparency	)	CMS-4187-P; RIN 0938-AT87
	)	

COMMENTS OF THE NATIONAL ASSOCIATION OF BROADCASTERS

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I. INTRODUCTION AND SUMMARY

The National Association of Broadcasters (NAB)[1] hereby comments on the Centers for Medicare & Medicaid Services (CMS) proposal to require direct-to-consumer (DTC) television advertising of prescription drugs and biological products to include the Wholesale Acquisition Cost (WAC) of the advertised drug or product.[2] Although NAB appreciates the significant concerns with the rising price of pharmaceuticals, NAB opposes this proposed rule. Adoption of the rule is unconstitutional, beyond the scope of CMS's statutory authority and would violate the Administrative Procedure Act (APA). It also unfairly and unjustifiably singles out television advertising, creating a disincentive for prescription drug and biological products manufacturers to advertise on television alone and therefore driving them to advertise on print media, social media and other outlets. Finally, the rule would significantly

[1] NAB is a nonprofit trade association that advocates on behalf of free local radio and television stations and broadcast networks before Congress, the Federal Communications Commission and other federal agencies, and the courts.

[2] CMS, *Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency,* Proposed Rule, CMS-4187-P, RIN 0938-AT87, 83 FR 52789 (Oct. 15, 2018) (Notice).

reduce or eliminate the substantial public interest benefits of drug advertising. In light of the proposed rule's multiple infirmities, we urge CMS not to adopt this rule.

II. THE WAC DISCLOSURE REQUIREMENT IS BEYOND CMS'S STATUTORY AUTHORITY AND OTHERWISE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT

A. CMS Lacks Statutory Authority to Adopt the WAC Disclosure Requirement

CMS lacks the statutory authority to adopt the proposed regulation. As an initial matter, NAB observes that the Department of Health and Human Services (HHS), like other federal agencies, "literally has no power to act . . . unless and until Congress confers power upon it."[3] In a previous case involving HHS specifically, the Supreme Court stated "[i]t is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."[4] Thus, if no statute confers authority, "a federal agency has none."[5]

While CMS admits that "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices,"[6] it nonetheless contends it has authority to do just that. It cites Section 1102 as authorizing the Secretary of HHS to issue "such rules and regulations . . . as may be necessary to the efficient administration of the functions . . .

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[3] *Louisiana Public Service Commission v. FCC*, 476 U.S. 355, 374 (1986).

[4] *Bowen v. Georgetown Univ. Hosp*., 488 U.S. 204, 208 (1988) (concluding that HHS lacked authority to promulgate retroactive Medicare cost-limit rule). *Accord Food and Drug Administration v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 161 (2000) (stating that an "agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress," and concluding that the FDA lacked authority to regulate tobacco products).

[5] *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001) (observing that a federal agency is a "creature of statute" and has "no constitutional or common law existence or authority, but only those authorities conferred upon it by Congress" and vacating certain rules as exceeding the EPA's authority).

[6] Notice at 52791.

under this Act,"[7] and Section 1871(a), which states, "The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title."[8] CMS contends that, since "Congress recognized the importance of administering the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures,"[9] CMS can use its general authority under the Act to issue rules that aim to reduce the costs of medication for Medicare and Medicaid patients.

NAB disagrees. Although CMS cites two very generalized grants of rulemaking authority, its proposed price disclosure rule is not reasonably tethered to CMS's specifically mandated duties or obligations. Court decisions involving very similar general grants of authority to other federal agencies demonstrate the flaws in the Notice's logic. For example, under Section 4(i) of the Communications Act of 1934, the Federal Communications Commission (FCC) is authorized to "perform any and all acts, make such rules and regulations, and issue such orders . . . *as may be necessary in the execution of its functions.*"[10] Despite its apparent breadth, the courts have nonetheless found this grant of rulemaking authority insufficient to permit the FCC to adopt certain specific rules when those rules were not tied to any of the FCC's "statutorily mandated responsibilit[ies]."[11] CMS

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[7] Notice at 52790 (citing Section 1102(a) of the Social Security Act).

[8] *Id.* (citing Section 1871 of the Social Security Act).

[9] Notice at 52791.

[10] 47 U.S.C. Sec. 154(i) (emphasis added).

[11] *Comcast Corp. v. FCC*, 600 F.3d 642, 661 (D.C. Cir. 2010) (concluding that the FCC lacked authority under Section 4(i) to regulate an internet service provider's network management practices because the FCC failed to tie its assertion of authority over this provider's internet service "to any statutorily mandated responsibility") (internal citations omitted); *see also American Library Ass'n v. FCC*, 406 F.3d 689, 700 (D.C. Cir. 2005) (explaining that the FCC's Section 4(i) authority is limited to circumstances where the FCC's general jurisdictional grant under the Communications Act covers the subject of the regulations and those regulations are reasonably ancillary to the Commission's effective performance of its statutorily

has not pointed to a specific statutory mandate for it to control prescription drug prices and, thus, the general grant of authority to the Secretary of HHS to prescribe rules necessary to administer the Social Security Act is an insufficient basis for adoption of the proposed rule.[12]

Even cases cited by CMS do not support its position. For example, *Thorpe v. Housing Authority of City of Durham*, 393 U.S. 268, 272 (1969), concerned a circular that the Department of Housing and Urban Development (HUD) issued directing local housing authorities to take certain steps with tenants before instituting eviction proceedings. Clearly, in *Thorpe*, HUD was exercising "efficient administration" authority. It prescribed the procedures by which an eviction can occur. That case is far different than this one, where CMS is attempting to create a new rule that is not concerned with the *administration* of the Social Security Act[13], but rather, is attempting to rely on Sections 1102 and 1871(a) as a means to develop a wholly new substantive – as opposed to administrative – rule for which it does not have a specific grant of authority.[14]

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mandated responsibilities, and vacating the challenged order as exceeding the scope of the FCC's authority).

[12] The list of unidentified provisions from the Social Security Act purportedly showing the general "importance of administering the Medicare and Medicaid programs" to "minimize[] unreasonable expenditures" do not provide such a mandate for the exercise of CMS's rulemaking authority here. Notice at 52791. The provisions are so incredibly specific that, rather than providing authority for the proposed rule, they confirm that if Congress had intended to regulate television advertising to reduce costs, it would have done so or directed a federal agency to do so. *See, e.g.,* Section 1902(a)(64) (State plans for medical assistance must provide a mechanism to receive reports and compile data on waste, fraud and abuse); Section 1936(b)(2) (directing the Secretary of HHS to enter into contracts to carry out such activities as "[a]udit of claims for payment for items or services furnished, or administrative services rendered, under a State plan under this title" pursuant to the Medicaid Integrity Program).

[13] As the Court in *Thorpe* noted, "[t]he circular imposes only one requirement: that the Authority comply with a very simple notification procedure before evicting its tenants." *Id.* at 278.

[14] Other cases also demonstrate the distinction between HHS's authority to adopt substantive rules pursuant to specific statutory authority and the lack of a basis for the

CMS also cites the fact that the Social Security Act requires price disclosures to the government in certain defined circumstances.[15] Far from supporting a conclusion that Congress has "generally endorsed" price disclosures, the specificity and narrowness of the two disclosure requirements cited demonstrates that if Congress had intended to impose a pricing disclosure requirement like the one proposed here, it would itself have adopted one (or specifically directed a federal agency to do so).[16] Agency reliance on general rulemaking authority, moreover, is regarded by the courts with even greater skepticism where, as here, an agency seeks to regulate speech.[17]

B. The WAC Disclosure Requirement is Arbitrary and Capricious

Even if CMS had authority to adopt the WAC disclosure requirement, which it does not, the requirement would fail because it is arbitrary and capricious. CMS simply has not

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proposed rule here. *See, e.g., Transitional Hosps. Corp. of La. v. Shalala*, 222 F.3d 1019, 1025 (D.C. Cir. 2000) (finding that Secretary had discretion to determine how to calculate the qualifying length of stay for hospitals because Congress provided "an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation") (internal citations omitted); *Illinois Council On Long Term Care v. Bradley*, 957 F.2d 305, 308 (7th Cir. 1992) (finding that certain provisions of the Medicaid Act and its implementing rules did not impose timeliness requirements on the payment of particular Medicaid claims, and observing that when Congress had wanted to impose time limits for the payment of Medicaid claims in other previous statutory provisions, "it did so explicitly").

[15] Notice at 52791 (citing requirements that manufacturers with Part B rebate agreements disclose pricing information to the government under Section 1927(b)(3)(A) and that sponsors offering prescription drug plans under Part D disclose the difference between price of a dispensed drug and the price of generic equivalent under Section 1860(k)(1)).

[16] *See generally Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452-53 (2002) ("it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion" of language in different sections of the same statute).

[17] *See, e.g., MPAA v. FCC*, 309 F.3d 796, 805-06 (D.C. Cir. 2002) (vacating FCC video description rules adopted pursuant to FCC's general rulemaking authority and concluding that affirmative grants of power from Congress are required for FCC to regulate speech). *Id.* at 805 ("Congress has been scrupulously clear when it intends to delegate authority to the FCC to address areas significantly implicating program content" because "such regulations invariably raise First Amendment issues").

drawn a rational connection between its proposed rules and the claimed ill it is attempting to remedy. Moreover, the proposed rules unlawfully single out one of many advertising mediums, and CMS provides no explanation for subjecting only advertisements shown on television to this new mandate.

It is well-established that a regulatory agency "must examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made."[18] The agency must be able to demonstrate that it has "engaged in reasoned decisionmaking—that it weighed competing views, selected [an alternative] with adequate support in the record, and intelligibly explained the reasons for making that choice."[19] The proposed WAC disclosure rule falls far short of this standard.

CMS contends that its proposed rules would increase transparency in drug pricing, thus inducing lower prices and more informed purchasing by beneficiaries. It observes that markets operate more efficiently when consumers have information about competing alternative products, including their prices.[20] CMS states that list price transparency will promote lower prices in two ways. First, CMS believes that disclosure will provide manufacturers with an incentive to reduce their list prices by exposing "overly costly" drugs to public scrutiny.[21] Second, CMS asserts that the disclosure will provide "some consumers with more information to better position them as active and well-informed participants in their health care decision-making."[22] CMS describes a series of steps that *may* cause

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[18] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983) (citations omitted) (*State Farm*).

[19] *FERC v. Elec. Power Supply Ass'n*, 136 S.Ct. 760, 784 (2016).

[20] Notice at 52789-90.

[21] *Id.* at 52792.

[22] *Id.*

disclosure of list prices to result in consumers choosing less costly alternatives.[23] CMS concludes that, "[u]ltimately, providing consumers with basic price information *may* result in the selection of lesser cost alternatives."[24]

Setting aside the apparent lack of certainty CMS itself has in the likelihood that price transparency will change consumer or provider behavior, it is important to note that the Notice also contains lengthy discussions of how manufacturer list prices — the prices proposed to be disclosed — are usually *not* what consumers actually pay.[25] It explains how third-party payment is a leading feature of health care markets, unlike others.[26] It discusses how negotiations between payors, Pharmacy Benefit Managers (PBMs) and manufacturers impact beneficiary cost sharing,[27] and how list prices do not reflect manufacturer rebates paid to a PBM, insurer, health plan, or government program.[28] Because of negotiations and rebates, the Notice explains, "a PBM could have ten different clients with ten different benefit designs and it would be possible that an employee from each client *could get the*

[23] Specifically, the WAC disclosure will provide the consumer with an "anchor price" or reference comparison to be used when making decisions about therapeutic options. Then, "conversations about a particular drug or biological and its substitutes *may* lead to conversations not only about price, but also efficacy and side effects, which in turn *may* cause both the consumer and the prescriber to consider the cost of various alternatives (after taking into account the safety, efficacy, and advisability of each treatment for the particular patient)." Notice at 52792 (emphases added).

[24] Notice at 52793 (emphases added).

[25] *Id.* at 52789-90.

[26] *Id.* at 52790.

[27] *Id.* at 52790.

[28] *Id.* at 52791.

exact same product and all ten could pay a different price."[29] Indeed, the Notice cites no evidence that any Medicare or Medicaid beneficiaries *ever* pay list price.[30]

Given that list prices so rarely reflect what consumers actually pay, disclosing that price cannot provide meaningful information to consumers that will "impact [their] own finances" or "positively affect the shared taxpayer responsibility to fund the Medicare and Medicaid drug benefit programs."[31] It is simply not clear how the facts found – in this case, how consumers rarely pay the list price – could lead to the conclusion that forced list price disclosure in television advertisements will have any impact on pricing. There is no rational connection between the proposed disclosure requirement and CMS's stated goal and, thus, the proposed rule is arbitrary and capricious.[32]

C. CMS Fails to Explain its Decision to Single Out Television Platforms and Disregards the Government's Substantial Governmental Interest in Free, Over-the-Air Television

The proposed rule also fails to meet APA standards because the agency provides no explanation for its decision to apply the rule exclusively to a single advertising medium. According to data cited by CMS, nearly one-fourth of drug manufacturers' total advertising budget is spent on media other than television. CMS inexplicably applies the rule *only* to television, excluding magazines, newspapers, websites and social media from its scope.[33]

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[29] Notice at 52790 (emphasis added).

[30] The Notice states only that a certain percentage of beneficiaries "in the commercial market" pay the full list price until they meet their deductible (but this data is not specific to Medicare and Medicaid beneficiaries). Notice at 52790.

[31] Notice at 52792.

[32] *See State* Farm, 463 U.S. at 43; *Burlington Truck Lines v. U.S.,* 371 U.S. 156, 168 (1962) (setting aside order of federal agency where it failed to articulate a "rational connection between the facts found and the choice made").

[33] According to the Notice, "[i]n 2017, over $5.5 billion was spent on prescription drug advertising, including nearly $4.2 billion on television advertising." Notice at 52792.

There is no discussion of any facts or reasoning the agency may have relied on in proposing to limit the rule's application to television advertising. The Notice offers only the conclusory statement that CMS considered, and rejected, the idea of applying the regulation to other advertising platforms.[34] This does not come close to meeting the agency's obligation to supply a reasoned explanation for its actions, and flies in the face of courts' expectations that an agency provide a sufficient explanation for treating similarly situated parties differently.[35]

This failure does not merely suggest that the television portion of the rule should be enacted while other forms of media are evaluated. In fact, CMS must assess the impact its rule could have on the television broadcast industry, especially in light of both the substantial public interest obligations the government already imposes on broadcasters, and Congress's past findings—upheld by the Supreme Court—about the substantial governmental interests served by free over-the-air television.

Television broadcast stations offer news, information and entertainment to the public over the air at no cost. Congress emphasized the importance of television broadcast stations when it enacted the mandatory carriage provisions of the Cable Television Consumer Protection and Competition Act of 1992 (1992 Act), finding that the provisions served three interests: (i) preserving the benefits of free, over-the-air local broadcast TV; (ii)

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[34] Notice at 52795 ("We considered whether this regulation should apply to advertisements that are in other media forums such as radio, magazines, newspapers, internet websites and other forms of social media, but concluded that the purpose of this regulation is best served by limiting the requirements to only those identified herein.").

[35] *Muwekma Ohlone Tribe v. Salazar,* 708 F.3d 209, 216 (D.C. Cir. 2013) ("Agency action is arbitrary and capricious if the agency offers insufficient reasons for treating similar situations differently.") (citations omitted). *Accord Chadmoore Communs. v. FCC*, 113 F.3d 235, 242 (D.C. Cir. 1997) ("We have long held that an agency must provide an adequate explanation before it treats similarly situated parties differently.").

promoting the widespread dissemination of information from a multiplicity of sources; and (iii) promoting fair competition in the market for TV programming. The Supreme Court agreed in *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622, 662-63 (1994) (*Turner I*), stating that these governmental interests were "important." The Court also noted that its review of the Cable Act and its findings persuaded the Court that Congress's overriding objective in enacting must carry was to preserve access to free television programming for those Americans without cable.[36] Among other things, the Court stated that the must carry "provisions are designed to guarantee the survival of a medium [broadcast television] that has become a vital part of the Nation's communication system, and to ensure that every individual with a television set can obtain access to free television programming."[37]

To support their production of original local news and public affairs programming, including coverage of emergencies, disasters and weather, television stations rely primarily on advertising revenue. Congress also has acknowledged the importance of advertising revenue to television station operations and stations' continued viability as a free service to the public that does not require a subscription.[38] Television broadcast stations already are competing with an ever-increasing array of other outlets for advertising dollars. A regulation

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[36] *Turner I*, at 646.

[37] *Id*. at 647. *See also* 47 U.S.C. § 521, notes, Congressional finding 10 (finding that "a primary objective and benefit of our Nation's system of regulation of television broadcasting is the local origination of programming. There is a substantial governmental interest in ensuring its continuation."). *Id.,* Congressional finding 11 (television broadcast stations are "an important source of local news and public affairs programming" and other programming that is "critical to an informed electorate.").

[38] 47 U.S.C. § 521, notes (Congressional finding 12) ("Broadcast television programming is supported by revenues generated from advertising over broadcast stations. Such programming is otherwise free to those who own television sets and do not require cable transmission to receive broadcast signals. There is a substantial governmental interest in promoting the continued availability of such free television programming, especially for viewers who are unable to afford other means of receiving programming.").

that creates disincentives to advertise on television interferes with the broadcast industry's primary revenue source, threatening local stations' ability to provide quality service to the public. An advertiser faced with the prospect of altering its television advertising to incorporate a government-scripted message with information that the advertiser may consider misleading to consumers may well opt to devote more of its advertising dollars to print, internet, or social media platforms.

Television broadcasters should be able to compete on equal footing with other media outlets for DTC advertising, and television viewers should not be excluded from the public interest benefits of DTC advertising.[39] Given the limits of the agency's statutory authority, its obligations under the APA, and the substantial governmental interest in free, over-the-air television broadcast service acknowledged by both Congress and the Supreme Court, CMS should not adopt the WAC disclosure requirement.

III. THE PROPOSED RULE VIOLATES THE FIRST AMENDMENT

NAB is a member of The Advertising Coalition (TAC), which is filing comments that discuss in detail why the proposed WAC disclosure requirement would be unconstitutional under the First Amendment.[40] Like other TAC members, NAB is concerned about the impact of any proposed regulation that affects the rights of advertisers to control their messages, as well as our nation's commitment to the First Amendment.[41] NAB agrees with the detailed First Amendment analysis of the proposed WAC disclosure requirement in the TAC Comments.

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[39] *See* Section IV, *infra* (discussing the public interest benefits of DTC advertising).

[40] *See* Comments of The Advertising Coalition (TAC), CMS-4187-P, RIN No. 0938-AT87 (Dec. 17, 2018) (TAC Comments).

[41] *Id.* at 2.

As discussed thoroughly in the TAC Comments, the proposed regulation violates the First Amendment rights of drug and biological product manufacturers.[42] "Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment."[43] In the seminal case on the constitutionality of restrictions on commercial speech, the Supreme Court held that commercial speech that is not false or deceptive and does not concern unlawful activities may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest.[44] As discussed in the TAC Comments, the proposed regulation does not satisfy the *Central Hudson* test because: (i) it is not clear that the government has a substantial interest in regulating advertising about pharmaceuticals when its goal is to regulate costs under Medicaid and Medicare; (ii) compelling list price disclosures cannot directly and materially advance CMS's stated interest of reducing Medicare and Medicaid expenditures on prescription drugs (in fact, the proposed rule does not have any rational connection to this goal); and (iii) compelling price disclosures bypasses less restrictive alternatives.[45]

Although the Notice suggests that the *Central Hudson* test should not apply and that a less stringent standard of review applied in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) would govern, CMS's interpretation of the caselaw is incorrect. The *Zauderer* standard only applies to disclosure requirements that are aimed at preventing

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[42] TAC Comments at 3-13.

[43] *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011).

[44] *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980).

[45] TAC Comments at 8-13.

misleading or deceptive commercial speech[46] and that involve the disclosure of "purely factual" and "uncontroversial" information.[47] Moreover, a speech regulation still will not pass muster under the *Zauderer* test if it is "unjustified or unduly burdensome."[48] As detailed in the TAC Comments, the proposed WAC disclosure cannot be analyzed under *Zauderer* because it is not aimed at preventing deception and does not mandate disclosure of purely factual or noncontroversial information.[49]

Even if the requirement were evaluated under *Zauderer,* it would not pass muster because it is unjustified and unduly burdensome.[50] It is unjustified because, as discussed above, the required disclosure of list prices lacks a rational connection to CMS' stated goal of reducing drug prices paid by Medicaid and Medicare recipients.[51] It unduly burdens the speech of drug advertisers by requiring them to deliver a scripted message[52] that they would

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[46] *Zauderer*, 471 U.S. at 651. *See also Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249-250 (2010) (applying *Zauderer* standard to a First Amendment challenge where the disclosure requirement "share[d] the essential features of the rule at issue in *Zauderer*" because the "required disclosures are intended to combat the problem of inherently misleading commercial advertisements"). There, the Court observed that regulations of speech that lack this essential feature would still be analyzed under *Central Hudson. Id.* ("The same characteristics of [the disclosure rule in *Milavetz*] that make it analogous to the rule in *Zauderer* serve to distinguish it from those at issue in *In re R. M. J.*, 455 U.S. 191 (1982), to which the Court applied the intermediate scrutiny of *Central Hudson*.").

[47] *Zauderer*, 471 U.S. at 651.

[48] *Id. Accord Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2377 (2018) (*NIFLA*).

[49] TAC Comments at 4-8.

[50] TAC Comments at 7-8.

[51] *See* Section II*, supra.*

[52] The proposed textual statement is as follows: "The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different."

not otherwise include in their advertisements,[53] ensure that the message appears at the end of the ad, with an adequate font and type size, against an appropriately contrasting background and for a length of time sufficient to be read easily,[54] and to update their advertisements as often as monthly if there are changes in the WAC.[55] Mandating WAC disclosures on the television medium alone also could drive drug companies to other platforms unaffected by this regulation.[56] The proposed WAC disclosure requirement is quite similar to the "government-scripted, speaker-based disclosure requirement" that was found to be "wholly disconnected from [the government's] informational interest" and struck down in *NIFLA*.[57]

CMS's claim that its proposed regulation is consistent with the First Amendment also fails to account for the regulation's potential harms to television broadcasting. The government's substantial interests in the preservation of free, over-the-air television broadcast service and promoting the widespread dissemination of information from a multiplicity of sources weigh heavily against imposition of this requirement, making the burden on speech proposed here even more unjustifiable. Indeed, broadcast television furthers First Amendment interests by promoting the widespread dissemination of

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[53] CMS acknowledges that prescription drug manufacturers tend not to provide pricing information in their advertising. Notice at 52970.

[54] Notice at 52799; Proposed rule 403.1203 (the textual statement "shall be presented at the end of an advertisement in a legible manner, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.")."

[55] Notice at 52799; Proposed rule 403.1201(d) (prices disclosed must be "for the most recent month for which the information is available").

[56] Notice at 52798 (discussing possibility that drug companies will find the cost of revising their ads to be prohibitively expensive and that TV drug advertising would be reduced).

[57] *NIFLA*, 138 S. Ct. at 2377.

information from a multiplicity of sources and providing information that is "critical to an informed electorate." By deterring advertising on broadcast television, the proposed rule threatens broadcast television's leading source of revenue and directly impacts the financial position of stations, contrary to important governmental interests asserted by Congress and upheld by the Supreme Court.[58]

In light of the First Amendment issues raised by the proposed rule, NAB urges CMS to consider alternative approaches that would better educate consumers about drug prices without burdening speech, including relying on the pharmaceutical industry's voluntary commitment to posting drug prices online.[59] Advertisements that refer audiences to online sources of information allow consumers to carefully review and digest detailed information, and to compare pricing and other data about competing products. Referring audiences to websites also is consistent with how consumers gather information today.[60]

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[58] *See* Section II. C., *supra.*

[59] PhRMA, *PhRMA Members Take New Approach to DTC Television Advertising,* Press Release (Oct. 15, 2018) (announcing updates to the pharmaceutical industry's voluntary DTC advertising guidelines to provide that television ads will "direct patients to information about medicine costs, including the list price of the medicine, out-of-pocket costs or other context about the potential cost of the medicine and available financial assistance.") The industry also is launching a new platform to provide patients, caregivers and providers with cost and financial assistance information for brand-name medicines, as well as other patient support resources. *Id*.

[60] *See, e.g., Amendment of Section 73.1216 of the Commission's Rules Related to Broadcast Licensee-Conducted Contests,* 30 FCC Rcd 10468, 10472 (2015) (unanimously adopting a rule permitting online disclosure of contest terms and conditions and finding that "[t]he Internet has become a fundamental part of consumers' daily lives and now represents the medium used most by the public to obtain information instantaneously."); Andrew Perrin and Jingjing Jiang, Pew Research Center, *About a quarter of U.S. adults say they are 'almost constantly' online* (Mar. 14, 2018) available at: http://www.pewresearch.org/fact-tank/2018/03/14/about-a-quarter-of-americans-report-going-online-almost-constantly/ (77% of Americans go online on a daily basis, including 26% who report that they are online "almost constantly").

IV. DTC ADVERTISING YIELDS IMPORTANT CONSUMER BENEFITS THAT WILL BE REDUCED OR ELIMINATED BY A WAC DISCLOSURE REQUIREMENT

Several consumer benefits arise from DTC advertising. DTC ads can raise awareness about medical conditions and treatment options, and spur consumers to action.[61] In an FDA consumer survey, 43% of respondents reported that a DTC ad caused them to look for more information either about the drug or their health, and 18% of respondents made an appointment to see a doctor about a medical condition they had never previously discussed.[62] Another study found that 25% of patients who visited their doctor after seeing DTC advertising received a new diagnosis, often for a high-priority health condition.[63] Data also show that DTC ads benefit consumers by encouraging patient adherence to treatment regimens,[64] reducing under-diagnosis and undertreatment of conditions,[65] promoting and

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[61] FDA, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results* (Nov. 19, 2004) at 2, available at: https://www.fda.gov/downloads/drugs/scienceresearch/researchareas/drugmarketingadvertisingandcommunicationsresearch/ucm152860.pdf (FDA Patient-Physician Study) ("DTC advertisements prompted a sizable percentage of patients to seek additional information about the drug, the condition it treats, or health in general."). *See also* TAC Comments at 15 (citing Princeton Survey Research Assocs. Int'l, *2017 Direct to Consumer Advertising Survey Results* (available at http://phrma-docs.phrma.org/download.cfm?objectid=325AA700-6BF9-11E7-929B0050569A4B6C).

[62] FDA Patient-Physician Study at 2.

[63] Auton F., *Opinion: The case for advertising pharmaceuticals direct-to-consumers*, Future Med. Chem. 2009; 1(4):587–592, 588 (citing Weissman J., *et al*., *Consumers' Reports on the Health Effects of Direct-to-Consumer Advertising* (2003), available at: http://www.npcnow.org/system/files/research/download/Consumer%20Reports%20on%20the%20Effects%20of%20DTCA.pdf).

[64] *See, e.g.,* FDA Patient-Physician Study at 69 (34% of physicians agreed that DTC increased the likelihood patients would use their medications properly; 32% agreed it would help patients adhere to their treatment regimen).

[65] *See* Ventola, C.L., *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?,* Pharmacy and Therapeutics. 2011 Oct; 36(10): 669-674, 681-684, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/#b31-ptj3610669 (discussing how ads for Procrit spurred chemotherapy patients who previously were not reporting fatigue

improving dialogue with health care providers,[66] and reducing the stigma associated with certain conditions.[67] A recent survey showed that although consumers taking action in response to DTC advertising are sometimes prescribed the drug advertised (55%),[68] their health care providers may also prescribe a different drug (54%), recommend over-the-counter drugs (41%), and/or encourage lifestyle changes (41%).[69]

DTC advertising thus has significant public interest benefits. But the proposed WAC disclosure could eliminate or reduce these benefits. First, the regulation may deter drug manufacturers from advertising on television. Broadcast television advertising can be an extremely valuable way for consumers to learn about medical conditions and available treatment options through DTC ads. Unlike many other media outlets, free over-the-air broadcast television does not require a subscription or any other payment. Television overall is used by 224.6 million Americans 18 years of age and older per week (91%), who are

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symptoms or receiving treatment to report fatigue to their doctors, leading to treatment). *See also* FDA Patient-Physician Study at 79-80 (72% of physicians agree that DTC makes patients aware of possible treatments; 44% agree that it increases patient awareness of health problems earlier).

[66] *See, e.g.,* FDA Patient-Physician Study at 69 (56% of physicians believe that DTC advertising makes patients ask better questions; 51% believe it leads to better discussions about the patient's health).

[67] *See* Auton F., *Opinion: The case for advertising pharmaceuticals direct-to-consumers*, Future Med. Chem. 2009; 1(4):587–592, 590 (a Merck advertising campaign for finasteride (Proscar), a treatment for benign prostatic hyperplasia, is widely regarded as having successfully raised awareness of a medical condition that men had been reluctant to discuss with their doctors).

[68] Kirzinger A., Wu B., Brodie M., *Kaiser health tracking poll – June 2018: campaigns, pre-existing conditions, and prescription drug ads,* June 27, 2018, available at: https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-june-2018-campaigns-pre-existing-conditions-prescription-drug-ads/.

[69] *Id*.

viewing an average of 5 hours 43 minutes per day.[70] Of the top 100 television programs among adults 18-49, 95 air on television broadcast stations.[71] With its significant reach, television broadcasting can be an excellent medium for advertisers to reach consumers and for consumers to learn new information about drug therapies. However, if adopted, this regulation could deter drug manufacturers from advertising on television platforms, reducing consumer access to information.

Second, to realize the benefits of DTC ads, consumers must be able to comprehend and absorb information in the ads. There is already a plethora of required disclosures in pharmaceutical advertising on television arising from FDA disclosure requirements, such as the major statement of risks.[72] Adding price information to the already complex array of disclosures in prescription drug advertising could overwhelm and confuse consumers. Research on advertising and communication recognizes the limits of a consumer's ability to process information.[73] The FDA has an open proceeding to consider whether its rules result

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[70] *Nielsen Total Audience Series Q1 2018*.

[71] Michael Schneider, *These Are the 100 Most-Watched TV Shows of the 2017-18 Season: Winners and Losers*, Indiewire (May 25, 2018), available at: https://www.indiewire.com/2018/05/most-watched-tv-shows-2017-2018-season-roseanne-this-is-us-walking-dead-1201968306/.

[72] 21 C.F.R. §202.1(e)(1).

[73] *See, e.g, See* Betts K.R., *et al., Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements*, Research in Social and Administrative Pharmacy (2017) at 2, available at: http:// dx.doi.org/10.1016/j.sapharm.2017.07.015 (Limited Risks Study) (observing that "[e]ven if consumers engage and process a thorough presentation of risk information, they may not be able to interpret and use the information because of constraints on working memory or information processing style;" this would make additional risk information "physically present but functionally absent") (citing Jacoby J., *Perspectives on information overload,* J Consum Res. 1984;10(4): 432e435. http://dx.doi.org/10.1086/208981; Wilson E.A., Wolf M.S., *Working memory and the design of health materials: a cognitive factors perspective,* Patient Educ Couns. 2009;74(3):318e322, available at: http://dx.doi.org/10.1016/j.pec.2008.11.005. *See also* Murray N.M. *et al*., *Public Policy Relating to Consumer Comprehension of Television Commercials: A Review and Some*

in risk statements that are too long and complex for broadcast advertisements, which can reduce consumer comprehension, minimize the most important risk information and potentially, result in therapeutic noncompliance caused by fear of side effects.[74] Even if the proposed pricing disclosure were lawful and reflected the price consumers would actually pay, it would add to an already complex and overwhelming disclosure regime, where every bit of information added may further reduce consumer comprehension.

As it stands, the proposed disclosure will only serve to confuse and mislead most consumers, resulting in yet another potential harm. While DTC ads have been shown to foster conversations with doctors about medical conditions, seeing a prohibitively (and deceptively) high price tag in a DTC ad may discourage consumers from inquiring about that drug, and may no longer trigger a visit to a health care provider that could have resulted in a diagnosis and treatment.[75] One recent analysis of the price of an anticoagulant showed that

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Empirical Results, 16 J. Consumer Pol'y 145, 155, 160-161, 164-165 (1993) (demonstrating that the number of words in a disclosure is negatively correlated with comprehension and that lack of viewer opportunity to process information disclosed in television advertising can contribute to reduction in comprehension); Murphy, J. & Richards, J., *Investigation of the Effects of Disclosure Statements in Rental Car Advertisements*, 26 J. Consumer Aff. 351, 355-356 (1992) (finding that if the amount of information presented exceeds consumers' ability to process it, the quality of consumer decision-making may be negatively affected). Murphy and Richards further state that "[a]lthough any efforts by regulators to facilitate informed decision-making may be laudable, failure to ensure that the chosen method of presentation is appropriate for consumer use can make those regulations worthless or even detrimental to consumer interests. If consumers are unable to understand or recall the information in the legally mandated form another disclosure technique…may be more efficacious." *Id*. at 373.

[74] FDA, *Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements*; Establishment of a Public Docket; Request for Information and Comments, Docket No. FDA-2017-N-2936, 82 FR 39598 (Aug. 21, 2017).

[75] Dusetzina S. and Mello M., *Disclosing Prescription-Drug Prices in Advertisements – Legal and Public Health Issues*, The New England Journal of Medicine, November 14, 2018 ("the proposal carries a risk of undercutting the main public health benefit of direct-to-consumer advertising: reducing rates of undertreatment").

although the WAC price was $419.00 per month, out-of-pocket costs to consumers range from $10.00 for commercially insured patients to $147 for Medicare beneficiaries.[76] A widely advertised type 2 diabetes drug has a WAC of $730 per month, but patients' actual costs could be much lower, and other treatments are available for as little as $4 per month.[77] WAC disclosure creates a significant risk that consumers who are ill might believe they cannot afford treatment and decide against seeking help. Even if the proposed rule were lawful, CMS should decline to adopt it because it poses significant potential harms to public health.

[76] Dusetzina S. and Mello M., *Disclosing Prescription-Drug Prices in Advertisements – Legal and Public Health Issues*, The New England Journal of Medicine, November 14, 2018.

[77] *Id.*

V. CONCLUSION

The proposed WAC disclosure requirement is unlawful under the APA and the First Amendment. It has the potential to drive advertising away from free, over-the-air television service, harming television stations' ability to meet the needs and interests of their local communities. It also could undermine one of the public interest benefits of DTC advertising. Rather than spurring consumers to have conversations about medical conditions with their health care providers, DTC ads with WAC disclosures may cause consumers to believe they cannot afford treatment, even though WAC prices rarely reflect what consumers will pay. Given the legal issues and public interest harms posed by the WAC disclosure proposal, NAB respectfully urges CMS to consider alternatives that will not inappropriately burden speech or confuse consumers.

Respectfully submitted,

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